

**K203523 Fixone hybrid knotless anchor**Dec 25, 2021  
389 days to decisionK203523 · Product code: **MAI** · Orthopedic  
Source: <https://www.510kdatabase.net/k203523/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Dec 1, 2020
Decision date	Dec 25, 2021
Days to decision	389 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aju Pharm Co., Ltd.</b>
Location	Seongnam-Si, KR
Contact	Kim Tae Hoon
510(k) history	10 submissions · 10 cleared · 2017-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Plusglobal</b>
Contact	Peter Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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